

REMARKS

Claims 45-53 are pending in this application, and the Examiner has rejected all of the claims.

WRITTEN DESCRIPTION REJECTION

The Examiner has maintained his rejection of claims 45-47 as allegedly lacking written description support in the specification under 35 U.S.C. § 112, first paragraph. In particular, the Examiner is concerned about the scope of the terms "at least a portion of a *pol* gene," "at least a portion of the nucleic acid sequence of a *pol* gene," and "at least one domain in a *pol* gene of HIV-1_{BRU}." The Examiner argues that the specification shows that Applicants were in possession of the full-length *pol* gene and fragments to *gag* and *env*. The Examiner believes that Applicants were not in possession of a large genus corresponding to Pol polypeptide fragments, nucleic acid sequences encoding them, or probes capable of hybridizing to the fragments under the recited conditions.

In responding to this rejection, Applicants have previously argued that that the Office should reconsider this rejection in light of the *Enzo* case. Applicants also argued that the conclusion that the general statements regarding fragments necessarily apply to the specific *env* and *gag* fragments, unduly limits the claimed invention to particular preferred embodiments. Finally, Applicants previously presented a declaration from Dr. Alizon stating that two plasmids discussed in the application contained at least a portion of the *pol* gene, based on the sequence information in the specification and the

restriction maps in *Clavel*. Additionally, the declaration stated that digestion and Southern blotting produced *pol* fragments because there is a PstI site at position 2481.

In response, the Examiner states that the *Clavel* publication discussed in the declaration does not provide nucleotide sequences for any of the inserts. The Examiner continues to argue that nothing in the specification or the *Clavel* publication would lead the skilled artisan to a particular *pol* fragment or polypeptide encoded thereby.

Additionally, the Examiner continues to be concerned that constructs disclosed in *Clavel* also contained other portions of the HIV-2 proviral genome. The Examiner states that pROD4 contains the *gag*, *pol*, and ancillary gene products. The pROD35 construct, according to the Examiner, comprises the *pol*, ancillary genes, *env*, and *nef* coding regions.

The Office Action, in the written description section, did not address Applicants' explanation regarding the sequence positions for the various plasmids disclosed. Applicants have previously stated that the pROD4.8 plasmid includes the entire *pol* gene, as it spans from 1457 (Hind III) to 5723 (Hind III). The pROD35 plasmid includes position 2658 (EcoRI) and continues to the 3' LTR, therefore containing a fragment of the *pol* gene from 2658 to 4936. Furthermore, the pROD27 plasmid includes the 5' LTR to position 2658 (EcoRI) and thus contains the part of the *pol* gene from 1829 to 2658. Additionally, Applicants have already stated that it is not necessary that pROD4 and pROD35 fall within the scope of the claims because the claims use the transition term "comprising," which allows for the presence of other coding regions.

As the Office appears to have continuing concerns about whether the sequence of these plasmids could be derived from the specification, in light of teachings in the art including *Clavel*, Applicants would like to explain how the skilled artisan could easily derive the position numbers.

In order to obtain these position numbers, the skilled artisan would first located the *pol* beginning and ending positions at 1829 and 4936 on the sequence. These positions are identified as the beginning and ending positions of *pol*, respectively, on page 22, line 14. The skilled artisan would then determine which restriction enzyme sites were within the *pol* sequence, using either a computer program designed for this purpose or locating restriction enzyme sites by hand. The restriction enzymes would be arranged in a pattern as shown in Figure 5 of the present application. See Figure 5, pROD35 and pROD27 plasmids. This information is also presented in the *Clavel* reference; Figure 3 of *Clavel* shows the restriction sites in the pROD35 and pROD27 plasmids.

Both plasmids contain at least a portion of the *pol* gene, and both contain the EcoRI restriction site. In order to obtain the reference to 2658, the skilled artisan would look for an EcoRI restriction site in the *pol* sequence. It is well recognized that EcoRI cleaves at GAATCC, between G and AATCC. This position is located on page 26 of the specification and could easily be located by the skilled artisan, either reviewing the sequences by hand or by using a computer program. In doing so, the skilled artisan would acquire the nucleotide sequence for the *pol* gene fragments pROD35 and pROD27 fragments.

Applicants note that, upon further consideration, the fragments claimed should be 1829-2658 and 2659-4936 because position 2658 will only be present in the 5' fragment after cleavage with EcoRI, while the 3' fragment will begin with 2659. Applicants have made this amendment in the current response.

Applicants continue to assert that two specific *pol* fragments are provided in the specification and that the skilled artisan would be able to ascertain the sequence of these fragments easily from information in the specification. If the Office doubts the reasoning presented and the evidence in the specification, Applicants request that the Office kindly explain the reasons for doubt, providing counterevidence to support any propositions relied upon. Therefore, Applicants request that the rejection be withdrawn.

NEW MATTER REJECTION

The Examiner has rejected claims 48-52 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. The Examiner disputes whether figures 5 and 6 and pages 26-28 of the specification support the rejected claims.

As discussed above, Applicants have explained how the position numbers in claims 48-52 have been derived from the specification in light of the prior art. The position numbers, therefore, are not new matter. There is no requirement that the limitations be present in a word-for-word or *in haec verba* format. So long as the limitations are supported in the specification through express, **implicit**, or **inherent** disclosure, the written description requirement has been satisfied. See MPEP § 2163(B).

Applicants therefore request that this rejection be withdrawn.

PATENT
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CONCLUSION

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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